Office Action Summary	Application No.	Applicant(s)	
	10/645,653	FREYMAN ET AL.	
	Examiner	Art Unit	
	CATHERINE N. WITCZAK	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *20110111* .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 25, 28, 29, 30, 31, 34 and 37-39 are rejected under 35 U.S.C. 102(e) as being anticipated by Heinrich et al (US 2005/0171563).

Heinrich et al disclose a device comprising a shaft (102); a self-expanding delivery member (114) shaped in a continuous solid cylindrical configuration (see Figures 1 and 7) made from a porous material; a therapeutic agent delivery lumen (112) in fluid communication with the delivery member (via 120); a retention member (104) configured and arranged to selectively collapse the delivery member; and a mechanism capable of applying negative pressure to the delivery lumen (see paragraph [0060], wherein Heinrich discloses a syringe being coupled to the delivery lumen - although Heinrich does not expressly disclose using the syringe to provide negative pressure, the structure of a syringe would inherently allow the syringe to be 'capable of applying negative pressure'; also see paragraph [0080] wherein Heinrich discloses the delivery lumen being in fluid communication with a source of aspiration);

As to claims 28 and 29, see paragraph [0075];

As to claims 30 and 31, see Figure 11;

As to claim 34, see Figure3;

As to claims 37-39, wherein the shaft lumen is fully capable of acting as a 'wire lumen'.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 25-35 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shippert (US 6,123,697) et al as modified by Shippert (US 6,123,697) as modified by Tanaka (US 5,395,309).

Shippert discloses a device comprising a shaft (124); a self-expanding delivery member (100) shaped in a continuous solid cylindrical configuration (see Figure 11 – top Figure) made from a porous material; a therapeutic agent delivery lumen (lumen of 124) in fluid communication with the delivery member (via 32); and a mechanism capable of applying negative pressure to the delivery lumen (52 wherein Shippert discloses a syringe being coupled to the delivery lumen - although Shippert does not expressly disclose using the syringe to provide negative pressure, the structure of a syringe would inherently allow the syringe to be 'capable of applying negative pressure');

As to claims 26, 27, and 40, see Figure 2;

As to claims 28 and 29, see column 5, lines 7-15;

As to claims 30 and 31, see Figure 11;

As to claim 32, see Figure 15, element 132;

As to claim 33, see Figure 11, element 120;

As to claims 34 and 35, see Figure 4;

As to claims 37-39, wherein the shaft lumen is fully capable of acting as a 'wire lumen'.

Shippert discloses the claimed invention except for disclosing a retention member arranged about the delivery member. Tanaka et al disclose in Figure 1 that it is known to use an applicator comprising a sheath surrounding an expandable nasal packing member. It would have been obvious to one having

ordinary skill in the art at the time of the invention to modify the device of Shippert with the teaching of Tanaka et al, since such a modification would simplify the insertion of the device of Shippert into the nasal cavity, by preventing the device from expanding (via the sheath member) until it has been properly positioned within the nasal cavity (see column 1, lines 5-20).

3. Claims 26, 27 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al as modified by Shippert (US 6,123,697).

Heinrich discloses the claimed invention except for disclosing expressly the syringe capable of providing irrigation/aspiration being a Luer syringe. Shippert discloses in Figure 5 that it is known to use a Luer syringe. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the device of Heinrich with a Luer syringe as taught by Shippert since Luer-type connections provide a secure connection between medical devices, and as such are frequently used as connectors on various medical devices. Thus, the modification of the device of Heinrich with a Luer syringe as taught by Shippert would provide the syringe of Heinrich with a syringe capable for providing a secure connection which would be compatible for use with a variety of medical devices.

4. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heinrich et al.

Heinrich et al disclose the claimed invention except for expressly disclosing the length of the delivery member. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the device of Heinrich et al with a device having a delivery member length between 5 and 40mm because Applicant has not disclosed that such a length provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would recognize that changing the dimensions of medical devices requires only routine skill in the art and is commonly employed in order to adapt device dimensions to meet the needs

of the specific situation/patient for which the device is being used. Therefore, it would have been an obvious matter of design choice to modify Heinrich et al to obtain the invention as specified in claim 36.

Response to Arguments

Applicant's arguments filed 1/26/11 have been fully considered but they are not persuasive. In regards to the Heinrich reference, Applicant argues that Heinrich fails to disclose a medical device comprising a self-expanding delivery member. Applicant also argues that it is improper for the fluid or liquid used to expand anchor 114 in Heinrich to also be considered a therapeutic agent for delivery and that Heinrich fails to disclose a porous material capable of releasing a therapeutic agent to an internal portion of a patient's body. Examiner disagrees. Heinrich discloses in paragraphs [0029], [0030], [0066], and [0105] 'a cover disposed over the radially expandable anchor to maintain the radially expandable member in an initial pre-expanded condition ... the radially expandable anchor is sized so that upon removal of the cover, the anchor expands.' As to Applicant's arguments that 'water, saline, sterile water and the like' are not therapeutic agents, Examiner maintains that the use of these fluids aids in the performing of Heinrich's medical (i.e. therapeutic) procedure, and as such act as therapeutic agents. Finally, Examiner points out that Heinrich teaches the anchors to be constructed of sponge-type and/or foam-type materials which are inherently porous and thus capable of releasing fluid.

In response to the Shippert reference, Applicant also argues that the device of Shippert is not 'self-expanding,' as the device in Shippert expands when it absorbs fluids. Examiner disagrees. If one were to argue that the device of Shippert is not 'self-expanding' because it requires the absorption of fluid in order to expand, one could just as easily argue that Applicant device is not 'self-expanding' as it requires removal of a retention member in order for the device to expand. Thus, in arguing that the Shippert reference is not self-expanding, it would also imply the Applicant's device is also not truly 'self-expanding.' It is the Examiner's position that 'self-expanding' refers to the ability of a device to take on a

different (i.e. self-expanded) state without additional user interaction - but only after that device has first been positioned/prepared by a user. In Applicant's device, that first positioning/preparing step would be that of the user withdrawing the retaining cover (which initially constrains the device) and thus allowing the device to 'self-expand' once the mechanical constraints have been removed. In the device of Shippert, the device first needs to be positioned/prepared by placing the device in a location in which fluids are present. Once this is done, the device of Shippert requires no further user interaction, and 'self-expands' as a result of the initially dry device absorbing fluid from its location causing the device to swell and self-expand. (Examiner would also like to point out that the same argument being made for the device of Shippert meeting the limitation of 'self-expanding' would also apply to those embodiments of Heinrich which do not teach the use of mechanical constraint, as the device of Heinrich-which is also an initially dry porous device-would likewise 'self-expand' once placed in to a location containing fluid which the device would absorb).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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